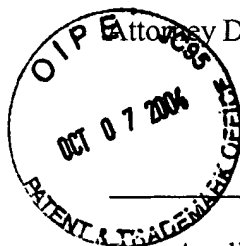


AF/1651
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Attorney Docket # 3029-75RCE

Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Tomohiro TSUJI et al.

Serial No.: 09/992,221

Filed: November 6, 2001

For: Method for Classifying and Counting Nucleated
Bone Marrow Cells

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner: J. P. Weber
Group Art: 1651

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October 5, 2004
(Date of Deposit)

Kent H. Cheng

Name of applicant, assignee or Registered Representative

Kent H. Cheng

Signature

October 5, 2004
Date of Signature

REPLY BRIEF

SIR:

This reply brief is being filed in triplicate pursuant to the provisions of 37 CFR §41.41 in order to respond to the Examiner's Answer mailed on August 6, 2004.

In the Examiner's Answer, the statutory basis of the rejection and the references relied upon for the rejection remain the same. However, the Examiner somewhat changes his reasoning for the rejection. In the previous Office Actions, the Examiner insisted that the fluorescent method and scattered light method were respectively equivalents to the absorption method and impedance method of Bentley. Therefore, the Examiner stated that it was obvious to combine the teachings of the other cited references with Bentley, thereby classifying fat particles and other cells as recited in the pending claims. Presently, the Examiner repeatedly emphasizes that Bentley is cited for the fact that it teaches the importance of classifying lipid particles. One of ordinary

skill in the art performing the analytical procedures of the other cited references would have been motivated by Bentley to have classified the lipid particles present in the marrow sample to ensure an accurate count. The cited references other than Bentley uses fluorescence and scattered light methods. Whether Bentley's particular analytic technique is equivalent to that of other cited prior art does not affect the rejection (see e.g. page 9).

Applicants respectfully disagree with the Examiner's above comments.

Inami discloses a method for differentiating erythroblasts from other cells in the blood and counting the same by measuring intensities of fluorescence and scattered light. Inami also mentions that the method can be applied to a bone marrow sample.

Kim et al. disclose a method for quantitative analysis of nucleated red blood cells by measuring scattered light and fluorescence.

Hansen discloses a method of identifying and enumerating cells of a subclass of lymphocytes by tagging lymphocytes with an antibody having a fluorescence response to an optical stimulation and detecting the fluorescence and the scattered light.

Hoffman discloses a method for discriminating between unstained and absorbing-dye stained cells by low angle and wide light scatter measurements.

In Kim '695, nucleated red blood cells are measured by using scattered light and fluorescence.

In sum, the inventors or authors in all of the above cited references detect fluorescence and scattered light in identifying or differentiating different cells. None of these references teaches or suggest the differentiation of lipid particles from other cells. Except for Inami, none of the other references tests or mentions bone marrow fluid.

The only remaining cited reference of Bentley is related to a method in which bone marrow fluid is measured by absorbance and aperture impedance.

None of the cited references teach or suggest a method that can differentiate erythroid cells, leucocytic cells and lipid particles in bone marrow fluid by determining the difference in intensities of the fluorescence and the scattered light.

To make the present invention obvious, the Examiner proposes to combine the teachings of Bentley and all the other cited references. It is Applicants' opinion that a person of ordinary skill in the art would not be motivated to make the modification as proposed by the Examiner. Specifically, Bentley detects absorbance and impedance whereas the other references detect fluorescence and scattered light in differentiating different types of cell. Bentley's method is totally different from methods of other references, as Applicants explained in detail in previous responses. Since the Examiner has given up asserting and relying on the proposed "equivalency" between the two substantially different analytical methods used by Bentley and other cited references, Applicants will not discuss this "equivalency" issue here.

However, since Bentley and the other cited references use totally different analytical methods, a person of ordinary skill in the art would not consider applying the teachings of Bentley to any of the other cited references for arriving at the method of the present invention.

Since a person of ordinary skill in the art would not be motivated to combine the teachings of the cited prior art, the present invention is not obvious under 35 U.S.C. 103(a).

Moreover, even if a person of ordinary skill in the art could have recognized the importance of classifying lipid particles and wished to differentiate the lipid particles from other types of cell by detecting fluorescence and scattered light methods, as the Examiner suggested, he or she would not expect any success of such a proposed modification. The method of

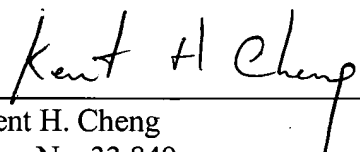
differentiating cells in the bone marrow or blood sample by fluorescence and scattered light is known from Inami, Kim '037, Hansen or Hoffman. Nevertheless, there is no teaching or suggestion in the prior art that lipid particles in the bone marrow can be differentiated by fluorescence and scattered light. Hence, Bentley cannot provide any basis for a person of ordinary skill in the art to reasonably expect that using another totally different method as discussed in Inami, Kim, Hanse or Hoffman can also successfully identify lipid particles.

Therefore, the element of "reasonable expectation of success" as required by U.S. patent law (see MPEP 2143.02) is not met in the present case. This constitutes another ground that the present invention is not obvious over the references cited by the Examiner under 35 U.S.C. 103(a).

The claims being patentably distinguishable from the art of record, reversal of the final rejections and early allowance are solicited.

It is believed that no fees or charges are required at this time in connection with the present application; however, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
COHEN, PONTANI, LIEBERMAN & PAVANE

By 
Kent H. Cheng
Reg. No. 33,849
551 Fifth Avenue, Suite 1210
New York, New York 10176
Tel (212) 687-2770

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